

REMARKS

Claims 1-4 and 11-13 are pending in this application. No amendment is made in this Response. It is believed that this Response is fully responsive to the Office Action dated **October 29, 2010**.

Claims 1-4, and 11-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,663,948. (Office action p. 3)

Reconsideration of the rejection is respectfully requested in view of the following arguments and the evidence in the attached Declarations under 37 CFR 1.132.

Applicant respectfully notes the Examiner's statement (page 4 of the Office action) that the claims are product-by-process claims, and that the patentability of product-by-process claims is determined by the product, not the process. Claim 1 was amended in the Amendment of June 2, 2010, to add a product-by-process limitation, with the calcium phosphate base particulate compound being obtained by steps (A), (B) and (C). However, on pages 10-11 of that Amendment, Applicants argued that the process limitation of claim 1 inherently produces a different product from that of Takiyama '948, and this argument was supported by evidence in the Declaration under 1.132 presented with that Amendment.

The Examiner maintains the argument that: "Since the calcium phosphate of '948 is made by a process similar to the process for making calcium phosphate [disclosed] in the instant invention, it is reasonably expected that the calcium phosphate of '948 is substantially similar to

that of the instant claims" (Office action, page 4, 1st full paragraph). This basic argument is repeated in the Response to Arguments on page 5 of the Office Action:

"Applicant's arguments filed 06/02/2010 have been fully considered but they are not persuasive.

The applicants argue that the prior art discloses the aging temperature is up to 97°C. The Examiner respectfully submits that the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the product was made by a different process. Since the prior art discloses a similar process of making calcium carbonate as that of the instant application, it is reasonably expected that calcium phosphate of '948 is substantially similar to that of the instant claims. The Applicants argue that the declaration filed on 06/02/2010 discloses the product of prior art is different from the product of the instant application. The Examiner respectfully submits that the applicant should conduct the experiment according to the teaching of prior art. For example the prior art disclose that the pH of the reaction is in range of 9-10 and the aging time is 0.1-100 hour."

In response, Applicant first of all responds to the Examiner's statement that: "Since the prior art discloses a similar process of making calcium carbonate as that of the instant application, it is reasonably expected that calcium phosphate of '948 is substantially similar to that of the instant claims."

Applicant submits that the process of the present invention **essentially differs** from that of the prior art '948 (hereinafter, referred to as "prior art"), in the following ways:

First, the prior art produces support particles (M) having a petaloid porous structure, then depositing a calcium phosphate compound (R) on the support particles (M), while the present invention does not require such support particles (M).

To explain the prior art process in more detail, Applicant has provided data on the prior art in the attached Declaration under 37 CFR 1.132 by Hidemitsu KASAHARA, signed February 23, 2011. This Declaration reproduces the prior art of '948, and provides TEM photographs of

the deposition steps from start to completing. Fig. A on page 4 of the Declaration shows sliced support particles (M1) having a petaloid structure, and Fig. B shows sliced composite particles (MR)(E1).

The steps from start to completion are illustrated in photographs (a)-(d) on page 5 of the Declaration, illustrating the steps of:

- (a): support particles (in a porous state),
- (b): deposition in early stage (Densification with a calcium phosphate compound is slightly progressed),
- (c): deposition in later stage (Densification with a calcium phosphate compound is almost completed),
- (d): deposition is completed (Densification with a calcium phosphate compound is completed).

That is, the prior art requires a two-step reaction, i.e., the production step of the support particles (M) and the deposition step of a calcium phosphate compound (R) on the support particles (M) for densification, while the present invention only requires one-step reaction and thus is very simple and economical as compared with the cited reference.

Second, the prior art does not require a heating step after the aging step, while the present invention requires a heating step after the aging step.

Third, the prior art conducts the aging step at 97 °C or lower, while the present invention conducts the heating step at 100 °C or higher.

Fourth, in the prior art, a water-soluble phosphate and an alkaline calcium compound are mixed to synthesize a calcium phosphate compound (R) in the presence of support particles (M)

wherein the calcium phosphate compound (R) is deposited on the support particles (M) to thereby obtain composite particles (MR) (col. 7, lines 6-19).

As the water-soluble phosphate, ammonium phosphate, sodium phosphate, etc., and used, and as the alkaline calcium compound, calcium carbonate is preferably used and colloidal calcium carbonate having an average particle size by DEM of 0.01-5 μm is more preferably used (col. 7, lines 51-67).

In contrast, in the present invention, a calcium compound and a water-soluble phosphoric acid compound are reacted (claim 5), and as the calcium compound, insoluble calcium compounds such as calcium carbonate are excluded and water-soluble or hardly soluble calcium compounds such as calcium chloride, calcium nitrate, etc., are used (page 15, line 6, to page 16, line 1, in the present specification).

By the essentially different processes as stated above, the products obtained are naturally different from each other; the product obtained by the present process is single-body particles while the product obtained by the prior art process is composite particles comprising support particles (M) and a calcium phosphate compound deposited thereon.

Further, the product of the present invention is excellent in thermal stability, in particular, satisfying $1 \leq T_g \leq 100$ (mg/g), which is limitation (b) of claim 1.

This thermal stability can be attained by:

(A) synthesizing calcium phosphate compound by reaction of a calcium compound and a water-soluble phosphoric acid compound in a pH range of 5 to 12,

(B) aging the obtained calcium phosphate compound for 0.1 to 24 hours, and

(C) heating the obtained calcium phosphate compound at 95 to 180° C.

Among the steps (A), (B) and (C), the step (C) is particularly important. As is demonstrated by the Declaration signed May 5, 2010, and filed on June 2, 2010, when, in the present invention, the heating temperature is changed to 97 °C, outside of the claimed range of 100 to 180 °C, the thermal stability is deteriorated to 126 mg/g (Add. Comp. Ex, 1), as compared with 91 mg/g at the heating temperature 100 °C, the lower limit of the claimed range (Add. Ex. 1).

With regard to the data presented in the Declaration filed on June 2, 2010, the Examiner now states:

"The Applicants argue that the declaration filed on 06/02/2010 discloses the product of prior art is different from the product of the instant application. The Examiner respectfully submits that the applicant should conduct the experiment according, to the teaching of prior art. For example the prior art disclose that the pH of the reaction is in range of 9-10 [sic] and the aging time is 0.1-100 hour."

Applicant notes that in the above wording, Applicant assumes that "in range of 9-10" is a clerical error and should have been --in the range of 8-10--.

In response to the above arguments, Applicant has obtained additional data, which are presented in the attached Declaration under 37 CFR 1.132 by Hideitsu KASAHARA, signed February 22, 2011.

In the experiments in this Declaration, since the prior art does not conduct the heating step after aging, as stated above, the heating temperature in the present process corresponds with the aging temperature in the prior art process. That is, the aging was conducted at 97 °C, the upper limit of the prior art process, which was closest to the heating temperature of 100 to 180°C of the present process.

Further, the heating treatment pH in the present process corresponds with the aging pH of the prior art process, and the aging was conducted at pH 8-10 disclosed by the prior art process.

Furthermore, the aging time was 1, 12 and 100 hours, respectively, which were closer to 0.1-100 hours disclosed by the prior art process.

The results are shown in Additional Comparative Ex. 2 to Additional Comparative Ex. 4 in Table B and the products obtained by those experiments have values of thermal stability Tg of 132 mg/g, 126 mg/g and 123 mg/g, respectively, which exceed the claimed range of $1 \leq Tg \leq 100$ (mg/g).

As stated above, the product of the present invention is produced by a process which is different from that of prior art, and as a result, the product of the present invention is inherently different from that of the prior art.

On page 2 of the Office action, under the heading "37 CFR 1.132" of the Office Action, the Examiner discusses the issue of criticality of the claimed range. In response, Applicant submits that the data presented in the Declarations of record adequately demonstrate a criticality commensurate in scope with the claim limitations. For example, the comparison of Add. Ex. 1 and Add. Comp. Ex. 1 in the Declaration filed June 2, 2010, adequately demonstrate that by a difference of only 3 °C, the thermal stability can be improved from 126 mg/g to 91 mg/g, which is an unexpected result fully commensurate with the claim limitations.

Again, Applicant submits that the evidence presented adequately demonstrates that the limitations of the present claims are not achieved by the product of U.S. Patent No. 6,663,948,

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Response filed February 24, 2011

Reply to OA dated October 29, 2010


and there is no suggestion in the reference for any modification of the preparative method that could achieve these limitations. The pending claims are not obvious over this reference.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Enclosures: Declaration under 37 CFR §1.132 signed on February 22, 2011
Declaration under 37 CFR §1.132 signed on February 23, 2011
Petition for Extension of Time